

PATENT
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APPLICATION FOR UNITED STATES PATENT

for

**AMPHIPHILIC MATERIALS
AND LIPOSOME FORMULATIONS THEREOF**

by

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BACKGROUND OF THE INVENTION

The present application claims priority to co-pending provisional application Serial No. 60/024,382, filed August 14, 1996, the entire text and figures of which disclosure are specifically incorporated herein by reference without disclaimer.

1. Field of the Invention

The present invention relates generally to the fields of lipid biochemistry and liposomes. More particularly, the invention provides amphiphilic molecules that incorporate a hydrophilic material or polymer attached to two or more spatially distinct hydrophobic residues. On contact with water, these amphiphilic molecules display surface activity and self-assemble into multimolecular aggregates and liquid crystalline phases. The invention thus also provides liposomes of enhanced stability that incorporate such amphiphilic molecules, and methods of using these formulations in a variety of applications in the fields of drug delivery, nutrition, bio-diagnostics, cosmetics, blood products and related applications.

2. Description of Related Art

Amphiphilic molecules are so named because the structures contain hydrophilic and lipophilic (hydrophobic) parts. The molecules distribute across air-water and oil-water interfacial boundaries and display surface activity. In oil and water mixtures, these help form and stabilize emulsions and co-dissolve other materials. When dispersed in water at concentrations above critical solubility limits, these can be induced to self assemble into a variety of spatially ordered molecular aggregates including micelles and lamellar bilayers which can entrap other molecules in the lipid and/or the aqueous compartments of the aggregates. Amphiphile-containing emulsions, micelle, and lipid lamellar bilayer aggregates are important vehicles for parenteral delivery of therapeutic agents and nutrients.

Liposomes are spherical vesicles of self-closed hydrated bilayers of amphiphilic lipids surrounding a generally central inner aqueous phase core which can differ in composition from the extraliposomal aqueous medium (Bangham and Horne, 1964). The lipid chains may be